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10/028,415	12/20/2001	Annette Lasham	11000.1004c3	4245

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EXAMINER
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VIVLEMORE, TRACY ANN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

## Office Action Summary

Application No.

10/028,415

Applicant(s)

LASHAM ET AL.

Examiner

Tracy Vivlemore

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-5, drawn to a method to modulate apoptotic cell death by modulating the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide, classified in class 514, subclass 44.
  - II. Claims 6-11, 14-16, drawn to a method to increase apoptotic cell death by reducing the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide, classified in class 514, subclass 44.
  - III. Claim 12, drawn to a method to modulate apoptotic cell death by modulating the binding of a transcriptional regulator of apoptosis to a regulatory polynucleotide, classified in class 514, subclass 44.
  - IV. Claim 13, drawn to a method to increase sensitivity of tumor cells to a DNA damaging agent, classified in class 514, subclass 44.
  - V. Claim 17, drawn to a method for increasing sensitivity to apoptosis by reducing the amount of cold shock protein, classified in class 514, subclass 44.
  - VI. Claim 18, drawn to a method of stimulating an immune response against an intracellular pathogen in a population of cells by reducing the amount of cold shock protein, classified in class 514, subclass 44.

- VII. Claim 19 and 22, drawn to a method of screening for an apoptosis modulatory agent by determining the level of a free transcriptional regulator in the cell, classified in class 514, subclass 44.
- VIII. Claim 20 and 22, drawn to a method of screening for an apoptosis modulatory agent by determining the level of mRNA transcripts, classified in class 514, subclass 44.
- IX. Claim 21 and 22, drawn to a method of screening for an apoptosis modulatory agent by determining the effect of the candidate agent on the expression of a reporter gene, classified in class 514, subclass 44.
- X. Claim 23, drawn to a method of identifying a cell population responsive to treatment with an apoptosis modulatory agent, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention I operates by modulating the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide. "Modulating the amount" can refer to an increase of a transcriptional regulator of apoptosis. Invention II operates by reducing the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide.

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3. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention I is to modulate the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide while the function of invention III is to modulate the binding of a transcriptional regulator of apoptosis to a regulatory polynucleotide.

4. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention I is to modulate apoptotic cell death while the function of invention IV is to increase sensitivity of tumor cells to a DNA damaging agent.

5. Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention I is to modulate apoptotic cell death while the function of invention V is to increase sensitivity to apoptosis by reducing the amount of cold shock protein.

6. Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case the different inventions have different functions. The function of invention I is to modulate apoptotic cell death while the function of invention VI is to stimulate an immune response against an intracellular pathogen in a population of cells by reducing the amount of cold shock protein.

7. Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention I is to modulate the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide while the effect of invention VII is to discover an apoptosis modulatory agent by determining the level of a free transcriptional regulator in the cell.

8. Inventions I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention I is to modulate the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide while the effect of invention VIII is to discover an apoptosis modulatory agent by determining the level of level of mRNA transcripts.

9. Inventions I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention I

is to modulate the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide while the effect of invention IX is to discover an apoptosis modulatory agent by determining the effect of the candidate agent on the expression of a reporter gene.

10. Inventions I and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention I is to modulate the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide while the function of invention X is to identify a cell population responsive to treatment with an apoptosis modulatory agent.

11. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention II is to reduce the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide while the function of invention III is to modulate the binding of a transcriptional regulator of apoptosis to a regulatory polynucleotide.

12. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of

invention II is to increase apoptotic cell death while the function of invention IV is to increase sensitivity of tumor cells to a DNA damaging agent.

13. Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention II is to increase apoptotic cell death while the function of invention V is to increase sensitivity to apoptosis by reducing the amount of cold shock protein.

14. Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention II is to increase apoptotic cell death while the function of invention VI is to stimulate an immune response against an intracellular pathogen in a population of cells by reducing the amount of cold shock protein.

15. Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention II is to reduce the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide while the effect of invention VII is to discover an apoptosis modulatory agent by determining the level of a free transcriptional regulator in the cell.



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16. Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention II is to reduce the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide while the effect of invention VIII is to discover an apoptosis modulatory agent by determining the level of level of mRNA transcripts.

17. Inventions II and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention II is to reduce the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide while the effect of invention IX is to discover an apoptosis modulatory agent by determining the effect of the candidate agent on the expression of a reporter gene.

18. Inventions II and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention II is to reduce the amount of a transcriptional regulator of apoptosis available to bind a target polynucleotide while the function of invention X is to identify a cell population responsive to treatment with an apoptosis modulatory agent.

19. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention III is to modulate apoptotic cell death by modulating the binding of a transcriptional regulator of apoptosis to a regulatory polynucleotide while the function of invention IV is to increase sensitivity of tumor cells to a DNA damaging agent.

20. Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention III is to modulate apoptotic cell death by modulating the binding of a transcriptional regulator of apoptosis to a regulatory polynucleotide while the function of invention V is to increase sensitivity to apoptosis by reducing the amount of cold shock protein.

21. Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention III is to modulate apoptotic cell death by modulating the binding of a transcriptional regulator of apoptosis to a regulatory polynucleotide while the function of

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invention VI is to stimulate an immune response against an intracellular pathogen in a population of cells by reducing the amount of cold shock protein.

22. Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention III is to modulate apoptotic cell death by modulating the binding of a transcriptional regulator of apoptosis to a regulatory polynucleotide while the effect of invention VII is to discover an apoptosis modulatory agent by determining the level of a free transcriptional regulator in the cell.

23. Inventions III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention III is to modulate apoptotic cell death by modulating the binding of a transcriptional regulator of apoptosis to a regulatory polynucleotide while the effect of invention VIII is to discover an apoptosis modulatory agent by determining the level of level of mRNA transcripts.

24. Inventions III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention III

is to modulate apoptotic cell death by modulating the binding of a transcriptional regulator of apoptosis to a regulatory polynucleotide while the effect of invention IX is to discover an apoptosis modulatory agent by determining the effect of the candidate agent on the expression of a reporter gene.

25. Inventions III and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention III is to modulate apoptotic cell death by modulating the binding of a transcriptional regulator of apoptosis to a regulatory polynucleotide while the function of invention X is to identify a cell population responsive to treatment with an apoptosis modulatory agent.

26. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IV is to increase sensitivity of tumor cells to a DNA damaging agent while the function of invention V is to increase sensitivity to apoptosis by reducing the amount of cold shock protein.

27. Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case the different inventions have different functions. The function of invention IV is to increase sensitivity of tumor cells to a DNA damaging agent while the function of invention VI is to stimulate an immune response against an intracellular pathogen in a population of cells by reducing the amount of cold shock protein.

28. Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention IV is to increase sensitivity of tumor cells to a DNA damaging agent while the effect of invention VII is to discover an apoptosis modulatory agent by determining the level of a free transcriptional regulator in the cell.

29. Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention IV is to increase sensitivity of tumor cells to a DNA damaging agent while the effect of invention VIII is to discover an apoptosis modulatory agent by determining the level of level of mRNA transcripts.

30. Inventions IV and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention IV

is to increase sensitivity of tumor cells to a DNA damaging agent while the effect of invention IX is to discover an apoptosis modulatory agent by determining the effect of the candidate agent on the expression of a reporter gene.

31. Inventions IV and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IV is to increase sensitivity of tumor cells to a DNA damaging agent while the function of invention X is to identify a cell population responsive to treatment with an apoptosis modulatory agent.

32. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention V is to increase sensitivity to apoptosis by reducing the amount of cold shock protein while the function of invention VI is to stimulate an immune response against an intracellular pathogen in a population of cells by reducing the amount of cold shock protein.

33. Inventions V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention V

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is to increase sensitivity to apoptosis by reducing the amount of cold shock protein while the effect of invention VII is to discover an apoptosis modulatory agent by determining the level of a free transcriptional regulator in the cell.

34. Inventions V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention V is to increase sensitivity to apoptosis by reducing the amount of cold shock protein while the effect of invention VIII is to discover an apoptosis modulatory agent by determining the level of level of mRNA transcripts.

35. Inventions V and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention V is to increase sensitivity to apoptosis by reducing the amount of cold shock protein while the effect of invention IX is to discover an apoptosis modulatory agent by determining the effect of the candidate agent on the expression of a reporter gene.

36. Inventions V and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention V is to increase sensitivity to apoptosis by reducing the amount of cold shock

protein while the function of invention X is to identify a cell population responsive to treatment with an apoptosis modulatory agent.

37. Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention VI is to stimulate an immune response against an intracellular pathogen in a population of cells by reducing the amount of cold shock protein while the effect of invention VII is to discover an apoptosis modulatory agent by determining the level of a free transcriptional regulator in the cell.

38. Inventions VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention VI is to stimulate an immune response against an intracellular pathogen in a population of cells by reducing the amount of cold shock protein while the effect of invention VIII is to discover an apoptosis modulatory agent by determining the level of level of mRNA transcripts.

39. Inventions VI and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention VI



is to stimulate an immune response against an intracellular pathogen in a population of cells by reducing the amount of cold shock protein while the effect of invention IX is to discover an apoptosis modulatory agent by determining the effect of the candidate agent on the expression of a reporter gene.

40. Inventions VI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention VI is to stimulate an immune response against an intracellular pathogen in a population of cells by reducing the amount of cold shock protein while the function of invention X is to identify a cell population responsive to treatment with an apoptosis modulatory agent.

41. Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of VII is to discover an apoptosis modulatory agent by determining the level of a free transcriptional regulator in the cell while the effect of invention VIII is to discover an apoptosis modulatory agent by determining the level of level of mRNA transcripts.

42. Inventions VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case the different inventions have different effects. The effect of invention VII is to discover an apoptosis modulatory agent by determining the level of a free transcriptional regulator in the cell while the effect of invention IX is to discover an apoptosis modulatory agent by determining the effect of the candidate agent on the expression of a reporter gene.

43. Inventions VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention VII is to discover an apoptosis modulatory agent by determining the level of a free transcriptional regulator in the cell while the function of invention X is to identify a cell population responsive to treatment with an apoptosis modulatory agent.

44. Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention VIII is to discover an apoptosis modulatory agent by determining the level of level of mRNA transcripts while the effect of invention IX is to discover an apoptosis modulatory agent by determining the effect of the candidate agent on the expression of a reporter gene.

45. Inventions VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention VIII is to discover an apoptosis modulatory agent by determining the level of level of mRNA transcripts while the function of invention X is to identify a cell population responsive to treatment with an apoptosis modulatory agent.

46. Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IX is to discover an apoptosis modulatory agent by determining the effect of the candidate agent on the expression of a reporter gene while the function of invention X is to identify a cell population responsive to treatment with an apoptosis modulatory agent.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group IV, restriction for examination purposes as indicated is proper.

### ***Conclusion***

47. Claim 22 appears in groups VII-IX. This claim is generic to all groups; it does not serve to link the inventions of groups VII-IX. If applicant elects any of these groups, this claim will be examined only to the extent that it relates to the claims of the elected invention.

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48. A telephone call was made to Janet Sleath on June 7, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

49. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

50. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

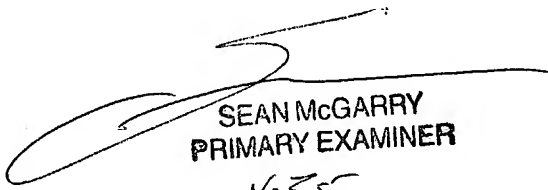
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tracy Vivlemore  
Examiner  
Art Unit 1635

TV  
June 3, 2004



SEAN MCGARRY  
PRIMARY EXAMINER  
1635